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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,653

04/09/2004

Paul D. Coleman

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23859 7590 01/11/2007  
NEEDLE & ROSENBERG, P.C.  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/821,653

Applicant(s)

COLEMAN ET AL.

Examiner

Jennifer Dunston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/04, 4/06, 10/06.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

### DETAILED ACTION

Receipt is acknowledged of an amendment, filed 4/9/2004, in which claims 2-56 were canceled. Currently, claim 1 is pending and under consideration.

#### *Priority*

It is noted that this application appears to claim subject matter disclosed in prior Application Nos. 09/770,534 and 09/178,170 and provisional application 60/063,274. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C.

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119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

It is noted that the reference to the prior filed applications was made at page 1, line 9. This is not the first sentence of the specification. Furthermore, the status of the nonprovisional applications should be included.

***Information Disclosure Statement***

Receipt of information disclosure statements, filed on 4/9/2004 and 4/18/2006, is acknowledged. The signed and initialed PTO 1449s have been mailed with this action.

The information disclosure statement filed 10/5/2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because dates were not provided for the references as required by 37 CFR 1.98(b)(5). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 25, line 16 and page 37, line 28.

### *Drawings*

The drawings are objected to because the description of Figure 7A refers to colors that cannot be seen in the black and white drawings. It would be remedial to amend the brief description of the drawings such that it describes the figure without referring to colors. Alternatively, corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

It is noted that color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

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The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase “antisense RNA transcripts from mRNA of each of the plurality of cells” are unclear. The phrase is unclear in that there is no verb for the positive action method step. One would not know what actions are encompassed by the claim to result in antisense transcripts. It would be remedial to amend the claim language to convert the phrase to a positive action method step.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Musselman et al (Reproductive Toxicology, Vol. 8, No. 5, pages 383-395, 1994; see the entire reference).

Musselman et al et al teach a method of profiling mRNA, comprising the steps of (i) isolating a plurality of cells each characterized by a different stage of disease progression as a result of the absence of phenytoin exposure or the presence of phenytoin exposure, (ii) synthesizing antisense RNA from the plurality of cells, and (iii) quantitating the levels of individual antisense RNA transcripts by slot blot hybridization, where hybridization is indicative of the levels of an mRNA for each of the plurality of cells obtained from a different disease stage (e.g. page 384-385, Materials and Methods; page 387, Slot blots and expression profiles; Figures 1 and 2).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Eberwine et al (The Neuroscientist, Vol. 1, No. 4, pages 200-211, 1995; see the entire reference).

Eberwine et al teach a method of profiling mRNA termed aRNA amplification, which comprises the steps of (i) isolating a population of cells or a single cell, (ii) annealing an oligo-dT primer that is extended at its 5'-end with a DNA sequence containing the T7 RNA polymerase promoter site to the mRNA, (ii) incorporating the primer into the cDNA by using reverse transcriptase, hence attaching a T7 RNA polymerase promoter site to each cDNA, (iii) converting the cDNA to double-stranded cDNA, which creates a functional T7 promoter site on



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each cDNA, (iv) synthesizing antisense RNA (aRNA) from the double-stranded cDNA template with T7 RNA polymerase, and (v) quantitating the levels of individual antisense RNA transcripts by hybridization or differential display, which is indicative of levels of an mRNA for each of the cells (e.g. page 201, left column, 1<sup>st</sup> full paragraph; page 202, left column, Amplified Antisense RNA (aRNA); page 203, right column; page 206, right column, 2<sup>nd</sup> full paragraph). Eberwine et al teach that the cells used in the method can be used to determine changes in mRNA expression as a function of disease state; thus, the method taught by Eberwine et al encompasses the use of cells at different stages of disease progression (e.g. page 209, left column, 1<sup>st</sup> full paragraph).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Eberwine et al (US Patent No. 5,723,290; see the entire reference).

Eberwine et al teach a method of profiling mRNA production during different disease stages, comprising the steps of (i) isolating neurons, (ii) converting an mRNA population into cDNA, making the cDNA double stranded, linearly amplifying the double stranded cDNA into antisense RNA (aRNA), and (iii) using the aRNA as a probe in a reverse phase Northern analysis or differential display analysis to produce an mRNA expression profile (e.g. column 2, lines 17-30; column 3, lines 12-36; column 5, line 21 to column 6, line 25). Eberwine et al teach that the method of the invention can be used to relate the presence or absence of synthesized proteins in a diseased state by determining the relative levels of mRNA expression in selected cells, preferably neurons, associated with the condition, and comparing the relative levels determined with established controls (e.g. column 6, lines 7-25). Eberwine et al are looking for abnormal

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levels of mRNA, thus the controls must encompass a control that does not have the disease (e.g. column 6, lines 7-25). Therefore, Eberwine et al teach the method for different disease stages.

### ***Conclusion***

The claim is not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.  
Examiner  
Art Unit 1636

jad

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

